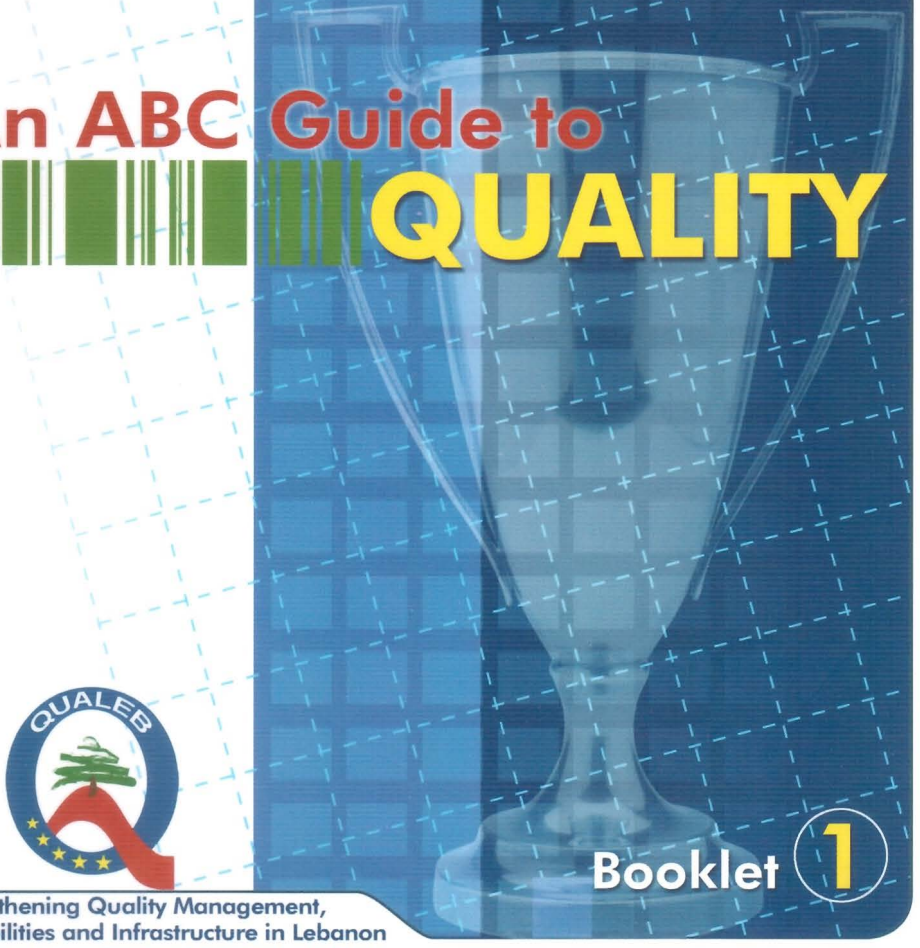
QUALEB

The Quality Programme

An ABC Guide to QUALITY



Booklet 1

Strengthening Quality Management,
Capabilities and Infrastructure in Lebanon

QUALEB
The Quality Programme

An ABC Guide to Quality

September 2005

This is one of a series of booklets produced by the Quality Programme, as a guide to understanding the role and importance of relevant quality issues

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List of Abbreviations

ATEX
Equipment explosive atmospheres
BSI
British Standards Institute
CEN
European Committee for Standardisation
EMC
Electromagnetic Compatibility
EU
European Union, made up of the 25 Member States
EC
European Commission
ISO
International Standards Organisation
PPE
Personal Protective Equipment
SME
Small and Medium Enterprises
SPS
Sanitary and Phytosanitary measures
(measures protecting public health)
TBT (WTO)
Technical Barriers to Trade (avoiding unnecessary technical obstacles to international trade)
WTO
World Trade Organisation

References to Terminology

Accreditation
a formal recognition that a body is competent to carry out specific tasks

Calibration
operation establishing the relationship between quantity values provided by measurement standards and the corresponding indications of a measuring system, carried out under specified conditions, including evaluation of measurement uncertainty

Certification
a third party evaluation of whether a product or system is in conformity with international standards

Customer Satisfaction
the marketing concept based on keeping the customer satisfied

CE Marking
Conformité Européenne, is an indication that the product complies with the essential health and safety requirements of the relevant EC directive(s) and that the product has been subject to a conformity assessment procedure

Conformity Assessment
a demonstration showing that the specified requirements relating to a product, process, system, person or body are fulfilled. Conformity assessment takes place before the product is brought to the market and includes activities such as testing, inspection and certification, as well as accreditation to conformity assessment bodies

Consumer Protection
laws and decrees with the objective of protecting the health and safety of consumers

Directives
European Union 'laws' to be implemented by member states

EU Single Market
formed by the member states of the European Community to create free movement of goods, persons, services and capital

Global Approach
Global Approach to conformity assessment. European Council Decision 90/683/EEC of 13 December 1990, replaced by European Council Decision 93/465/EEC of 22 July 1993 sets out more detailed specifications on testing and certification procedures and provides guidelines for the use of CE conformity marking

HACCP (Hazard Analysis and Critical Control Points)
systematic method used in the food industry to identify potential food safety hazards, so that key actions, known as Critical Control Points (CCP's), can be taken to reduce or eliminate the risk of the hazards being realised

Harmonised Standards
standards developed and adopted in the framework of a European New Approach Directive by the European Standards Organisations, CEN, CENELEC, ETSI, on the request (mandate) of the European Commission. Harmonised Standards cover only technical aspects and/or testing methods related to the essential health and safety requirements. Technically harmonised standards do not differ from normal standards; the difference is in the legal consequences. Application of harmonised standards by a manufacturer leads to the presumption that the product is compliant with the essential health and safety requirements.

Market Surveillance
actions taken by the authorities to ensure that products are compliant with the requirements laid down in technical regulations

Metrology
field of knowledge concerned with measurement: it includes all theoretical and practical aspects of measurement, whatever the measurement uncertainty and field of application

Metrological Traceability
a property of a measurement result relating the result to a stated metrological reference, through an unbroken chain of calibrations of a measuring system or comparisons, each contributing to the stated measurement uncertainty

New Approach Directives
European Commission directives harmonising national technical legislation within the European Union, requiring obligatory CE-marking. Member states have an obligation to transpose them into their national legislation

National Quality Policy
the overall direction and strategy of a Government towards the field of quality

New Approach

a New Approach to 'technical harmonisation and standards', providing a new framework for the harmonisation of national regulations for industrial products. The New Approach was devised to facilitate the achievement of the Internal Market and to encourage flexible and technology-neutral legislation, thus promoting innovation and competitiveness

Notified Bodies

approved competent bodies that are part of the Conformity Assessment chain

Product Liability

a legal obligation of a producer to compensate for damage caused to human beings, animals and property, by a product defect

Quality Marks

a readily identifiable label issued by a group of manufacturers

Quality Chain

all the elements related to the quality concept, linked together – similar to quality infrastructure

RAPEX

a rapid exchange of information between market surveillance authorities in the EU, on the dangers arising from the use of consumer products

RASFF (European Union Rapid Alert System for Food and Feed)

a procedure to inform the Member States when a product presents a serious risk for the health and safety of consumers; the system was extended to include all food and feed products, finally destined for human consumption

Standard

a published specification that establishes a common 'language'; it contains a technical specification, a testing method or terminology and is designed to be used consistently as a requirement, a guideline or a definition

Standardisation

a way to facilitate interchangeability and interoperability, reducing technical barriers to trade - also the process of establishing a technical standard

The references for this terminology are ISO 9000, IS0 17000 and ISO VIM

1. WHAT IS QUALITY?

Quality represents **a new strategic philosophy of enterprise management**, based on the overall commitment of management and employees, towards customer satisfaction and continuous improvement of products, production and services.

> 'Quality' is defined as the totality of features and characteristics of a product or service that impact on its ability to satisfy a given need or requirement; also described as 'fitness for purpose' or 'value for money', as perceived by the customer.
>
> According to **ISO 9000**, quality is a characteristic that a product or service must have; a quality product or service is one that meets the needs and expecations of customers

The European Union (EU) has agreed that quality concerns the product or the service at a competitive price. Ensuring good quality of products and services, is an **ethical obligation** for all those involved in the quality chain.

2. QUALITY INFRASTRUCTURE

The Quality Infrastructure is normally associated with quality management, quality assurance and quality control, certification and accreditation, conformity assessment, quality marks and labels, standardisation, metrology, testing, market surveillance etc.

A Quality Infrastructure operates on the basis of a number of components taking into account the needs, resources and limitations of the society.

3. NATIONAL QUALITY POLICY

A National Quality Policy defines the goals and actions of a nation, in the context of quality. Such a policy has to be explicitly explained and harmonised with international and regional needs and know-how. It also has to be accepted and applied by governments as well as non-governmental organisations, in order to increase the competitiveness of national products and services, facilitate the dynamic diffusion of a quality culture, strengthen the quality infrastructure and finally support international trade.

The European Commission's role in developing **Quality Policies** is to act as a facilitator, working with key European, national and international players.

The European Commission recognises the particular needs of SMEs and has taken into consideration the market needs for a homogeneous, transparent and credible quality environment within which public authorities, economic operators and users/consumers, can have complete confidence.

4. IMPORTANCE OF QUALITY IN WORLD MARKETS

In current world markets, both manufacturers and consumers require guarantees for the quality of their products and services. It is no longer sufficient to provide products and services that conform to certain requirements only, rather all manufacturers and service organisations must be in a position to demonstrate their capacity and capability, to provide guaranteed quality for their products and services, on a continuous basis.

This is why all businesses and public organisations need to set up quality systems, enabling them to guarantee that the required quality is obtained at the appropriate cost, while also taking into consideration environmental or social accountability concerns, as required.

5. BENEFITS OF ADOPTING A QUALITY SYSTEM

Quality systems are integral parts of international competitiveness. The implementation of quality systems constitutes for enterprises and in particular for SMEs, an important way of showing that they fulfill the requirements of a new market economy.

A quality system or quality management system (see below) is a very powerful concept which integrates rigorous engineering with concepts of value, human and customer satisfaction and continuous improvement, in the struggle for excellence, in all kinds of work.

6. ADVANTAGES FOR SMALL AND MEDIUM ENTERPRISES

When comparing Small and Medium Enterprises (SMEs) with large companies, one obvious advantage of the SME is that quite often it is a family-owned business, with a Director who is often, the owner of the business. Consequently, he/she is directly motivated to lead the company to prosperity, by satisfying existing customer needs and attracting new clients/customers.

The informality of the management of such a business may also provide further advantages. The Director/owner gives verbal instructions on who does what and how. While he/she provides constant guidance, employees are instructed to carry out follow-up checks and controls on the quality of products/services.

> It is not necessary for an SME to install a cumbersome quality management system in the company; implementation of a quality system, which was designed for a larger organisation, is a common mistake that paralyses many small businesses.

In general, all businesses have an established method or system for conducting their business activities. As explained above, in a small company, informality can be quite effective. However, it is rarely documented.
A quality management system identifies those features that can help a business to consistently meet the expectations of its customers.

7. QUALITY MANAGEMENT SYSTEMS

A quality management system is simple in its basic concept; it seeks to:

- Identify external quality related input requirements specified in licences to trade, regulations, specific customer requirements and chosen management system standard(s)
- Ensure that all these input requirements have been addressed within the management system, at the appropriate location in terms of defined specific system requirements
- Ensure that company personnel receive appropriate training in system requirements
- Define performance measures, as applicable to the system requirements
- Generate the result or evidence that the system requirements have been executed
- Measure, monitor and report the extent of compliance with these performance measures
- Continually monitor changes to input requirements and ensure that these changes are reflected in changes to the specific system requirements, when applicable
- Audit and evaluate the system processes and correct them, when applicable
- Provide a culture and process for continually improving the system embracing feed-back and lessons learned, into the system
- Evaluate customer satisfaction and take corrective action, as necessary

Quality management systems refer to what the organisation does to manage its processes or activities. In very small organisations, there is probably no 'system' as such, just 'our way of doing things' and 'our way' is probably not

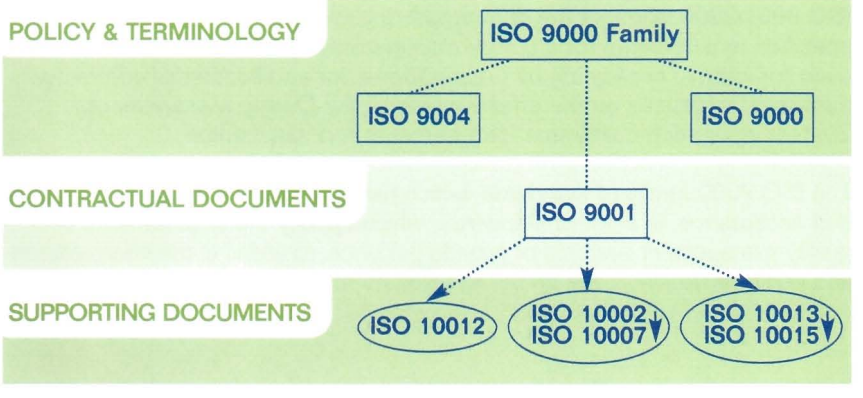
written down or documented, but it is all in the head of the manager/owner and employees.

The larger the organisation is and the more people are involved, the more the likelihood is for written procedures, instructions, forms or records. This more formal approach helps to ensure that everyone is not just 'doing his / her thing' but that there is a minimum of order, in the way the organisation deals with its business. Accordingly, time, money and other resources are utilised efficiently. To be really efficient and effective, the organisation can manage its way of doing things by systemising it. This ensures that nothing important is left out and that everyone is clear about who is responsible for doing **what, when, how, why and where.**

Quality management system standards provide the organisation with a model to follow, in setting up and operating the management system. This model incorporates the features which experts in the field have agreed upon, as representing the 'state-of-the-art'. A management system, that follows the model, is built on a firm foundation of 'state-of-the-art' practices.

The best way of creating a quality system is by adhering to a quality management system standard, which identifies those features that can help a business to consistently meet its customers' requirements. Quality management systems are about evaluating how and why things are done, writing down how things are implemented and recording the results, to show that the actions have been carried out.

8. THE ISO 9000 FAMILY OF STANDARDS



The British Standards Institution (BSI) launched its first management system standard, BS 5750 Quality Management System, in 1979. On the basis of this standard, the International Organisation for Standardisation (ISO), launched the ISO 9000 standard worldwide, in 1987.

In 1994 and 2000, ISO published new versions of the ISO 9000 family of standards for voluntary worldwide use, known as **generic management system standards.** Generic means that the same standards can be applied to any organisation, large or small, whatever its product is – even if its 'product' is actually a service – in any sector of activity and whether it is a business enterprise, a public administration, or a governmental department. At European level, the ISO standards are issued by the European Standardisation Body (CEN) under the classification EN-ISO-'...' standard.

> **ISO 9000** is concerned with 'quality management' in defining what the organisation does to enhance customer satisfaction, by meeting customer and applicable regulatory requirements and to continuously improve its performance in this regard.

ISO 9000 is concerned with the way an organisation deals with its work and not directly the result of this work. In other words, ISO 9000 involves processes and not products – at least, not directly. Nevertheless, the way in which the organisation manages its processes is obviously going to influence its final product. In the case of ISO 9000, it is going to affect whether or not everything has been done to ensure that the product meets customers' requirements.

Such a philosophy is best described in the **ISO 9004** standard which provides the principle rules a company must comply with, in implementing a Quality Management System. The reference to **ISO 9001** is a further step in the process, if the company is planning to achieve certification by a third party.

ISO 9001:2000 is in fact the contractual document for being assessed – it specifies requirements for a quality management system so that it can be used for internal application by organisations, for certification or contractual purposes. It focuses on the effectiveness of the Quality Management System in meeting customers' requirements and satisfaction.

The ISO 9000 family of standards, which has gained international recognition and acceptance, is a set of standards, which specify the requirements of quality management systems or provide guidance, to assist in the interpretation and implementation of the quality system, as follows:

ISO 9000:2000 *Quality management systems / Fundamentals and vocabulary*

Establishes a starting point for understanding the standards and defines the fundamental terms and definitions used in the ISO 9000 family to avoid misunderstandings in their use.

ISO 9001:2000 *Quality management systems / Requirements*

This is the requirement standard used to assess your ability to meet customer and applicable regulatory requirements and thereby address customer satisfaction. It is now the only standard in the ISO 9000 family against which third-party certification can be carried.

ISO 9004:2000 *Quality management systems Guidelines for performance improvements*

This guideline standard provides guidance for continuous improvement of the quality management system for the benefit of all parties, through sustained customer satisfaction.

Together with the above family of standards, ISO prepared supporting documents as guidelines for technical reports, which make up the ISO 9000 family *(see below)*.

ISO 10002:2004 *Quality management systems / Customer satisfaction Guidelines for complaints handling in organisations*

Provides guidance on the process of complaints handling related to products, including planning, design, operation, maintenance and improvement.

ISO 10005:2005 *Quality management systems / Guidelines for quality plans*

Provides guidelines to assist in the preparation, review, acceptance and revision of quality plans.

ISO 10006:2003 *Quality management systems Guidelines to quality management in projects*

Guidelines to help ensure the quality of both the project's processes and products.

ISO 10007:2003 *Quality management systems Guidelines for configuration management*

Gives guidelines to ensure that a complex product continues to function when components are changed individually.

ISO 10012:2003 *Measurement management systems / Requirements for measurement processes and measurement equipment*

Provides guidelines on the main features of a calibration system to ensure that measurements are made with the intended accuracy.

ISO/TR 10013:2001 *Guidelines for quality management systems documentation*

Provides guidelines for the development and maintenance of documents, tailored to specific needs.

ISO/TR 10014:1998 *Guidelines for managing the economics of quality*

Provides guidance on how to achieve economic benefits from the application of quality management.

ISO 10015:1999 *Quality management / Guidelines for training*

Provides guidance on the development, implementation, maintenance and improvement of strategies and systems for training that affects the quality of products.

ISO 19011:2002 *Guidelines for Quality and/or Environmental Management Systems Auditing*

Provides guidelines for verifying the system's ability to achieve defined quality objectives - this standard can be used internally for auditing suppliers.

The ISO 9000 quality management system standards have proved that they can play an essential role in quality assurance and are implemented by more than 500,000 organisations in 150 countries. ISO has also issued standards for Environmental management systems (ISO 14001).

9. AN OVERVIEW OF ISO 9001 STANDARD

The revision of the ISO 9001 standard in the year 2000 contains five requirement sections, each dealing with one of the fundamental building blocks required in any process. These are:

1. Quality management system - this section details the general and documentation requirements that are the foundation of the management system. The general requirements highlight the processes of the management system, how they interact with each other, what resources are needed to run the processes and how to measure and monitor the processes. The second part of the section sets out the requirements for the documentation needed and the way of controlling it, so that the system operates effectively.

2. Management responsibility - the management of the system is the responsibility of 'top management' at a strategic level in the organisation. 'Top management' must be aware of its customers' requirements, at a strategic level and must make a commitment to meet these needs, in addition to setting up statutory and regulatory requirements. 'Top management' must also set policies to plan on how the objectives will be met. They should also ensure that there are clear internal communications and that the management system is regularly reviewed.

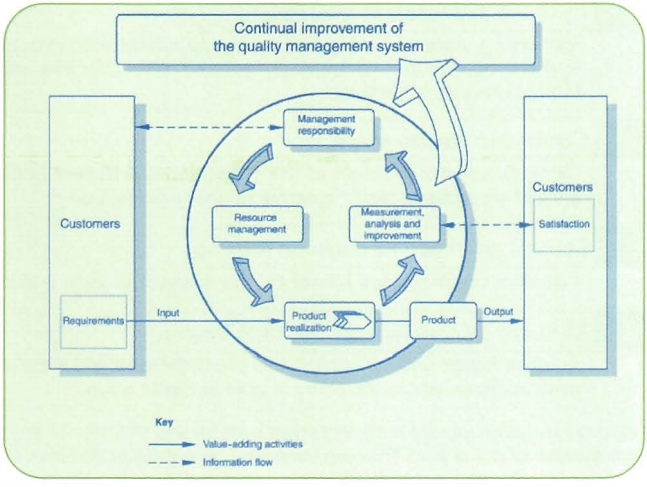
3. Resource management - this covers the people and physical resources needed to carry out the process. People should be competent to carry out their tasks; besides, physical resources and work environment must be capable of ensuring that customers' requirements are met.

4. Product/Service realisation - these are the processes necessary to produce the product or provide the service. This is the activity associated with converting the inputs of the process into outputs. For example, in a manufacturing organisation, this may be the process

of converting iron ore to steel, via a blast furnace. For a service organisation, this may be the process of moving a product or person from one place to another (a taxi journey).

5. Measurement, analysis and improvement - these are the measurements to enable the systems to be monitored and to provide information on how the systems are performing with respect to customers, the management systems themselves through internal audits, the processes and the product. Analysing these issues, including any defect or shortfall in performance, will provide valuable information to be used in improving the systems and products, as the need arises.

Each of these five fundamental building blocks is required for any process because, if one of the blocks is missing, a controlled process is not in place. This is recognised in the standard and represents a shift to viewing the quality system as a series of processes, set out as follows:



Model of the ISO 9001 process-based quality management system

10. QUALITY MANAGEMENT PRINCIPLES

A quality management principle is a comprehensive and fundamental rule or belief for leading and operating an organisation, aimed at continuously improving performance over the long term, while focusing on customers' needs and addressing the needs of all other stakeholders.

The ISO 9000:2000 series are based on eight quality management principles. These principles can be used by senior management as a framework to guide their organisations towards improved performance. The principles are derived from the collective experience and knowledge of international experts.

Principle 1 **Customer focus**

Organisations depend on their customers and therefore should understand current and future customer needs, meet customer requirements and strive to exceed customer expectations.

Principle 2 **Leadership**

Leaders establish unity of purpose and direction of the organisation. They should create and maintain the internal environment in which people can become fully involved in achieving the organisations' objectives.

Principle 3 **Involvement of people**

People at all levels are the essence of an organisation and their full involvement enables their abilities to be used for the benefit of the organisation.

Principle 4 **Process approach**

A desired result is achieved more efficiently when activities and related resources are managed as a process.

Principle 5 **Systems approach to management**

Identifying, understanding and managing interrelated processes as a system, contributes to the organisations' effectiveness and efficiency in achieving its objectives.

Principle 6 **Continued improvement**

Continuous improvement of the organisations' overall performance should be a permanent objective of the organisation.

Principle 7 **Factual approach to decision making**

Effective decisions are based on the analysis of data and information.

Principle 8 **Mutually beneficial supplier relationship**

An organisation and its suppliers are interdependent and a mutually beneficial relationship enhances the ability of both to create value.

As a rule, all organisations operate a management system and virtually, all employ a 'formal' management system of some sort. Few organisations do not issue documented invoices, maintain accounts or prepare contracts of employment and job descriptions/specifications for their employees. Implementing quality management, amounts to building the eight quality management principles of ISO 9000 onto this foundation. The illustration below sets out the quality management system model in its simplest form.

11. IMPLEMENTING A QUALITY MANAGEMENT SYSTEM

The first and most important task for an SME undertaking the implementation of a quality management system is to establish the reasons and justification for doing so. The driver for the implementation of a Quality Assurance System must have the motivation and willingness, to improve the quality of the products and the company's performance.

If the sole driver is to obtain an ISO 9001 certificate to get on customers tender lists, there is a danger that the system will simply focus on the ISO standard. The result may not serve any useful purpose and simply act as a drain on the resources of the organisation. By developing the system, based on the process of implementation (Process of implementation and certification, (Chapter 12 Certification), the result should be a satisfactory and useful system. This approach sets out the basic stages to be followed.

Independent consultants or experts can also play a useful role in this context, whose job must be to facilitate and support the on-going process. It is not the consultant's role to write the manual or draft the procedures, as the consultant does not know the company's procedures in detail. However, he/she can greatly assist in identifying the core processes and 'audit' the procedures drafted by the company.

The aims and goals for the implementation of a quality management system are usually based on an organisation's need for:

- Performance improvement and increase in bottom line profit
- Effective management of risk
- Quality Assurance of products or services towards customers
- Basis for implementing a culture of opportunity
- Certification to ISO 9001, if required, as the method used for international acceptance of products and services

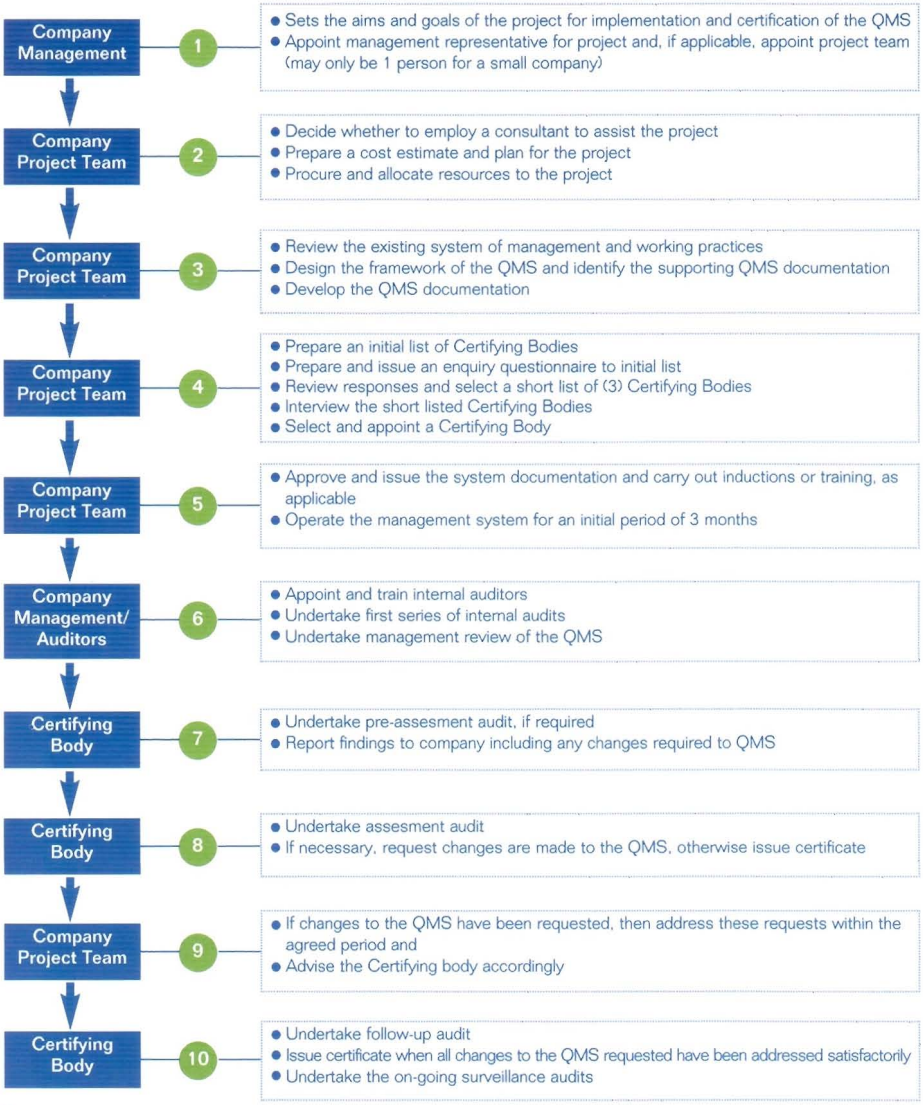
12. CERTIFICATION

Third Party certification to ISO 9001 is an option available to the company, when required by particular clients or the needs of the market. There are many advantages in implementing ISO 9001:2000 and achieving certification.
In summary, these are:

- Improvement in 'bottom line' profit through:
  - Better efficiency
  - Continual improvement
  - Less waste
- Consistent control of key processes
- Possible reduction in insurance premiums
- Promotion and standardisation of good working practices

- Greater marketing appeal and improved public relations
- Meeting the requirements for inclusion on some tender lists
- Providing incentives for training employees
- The effective management of risk
- Providing incentives for introducing an opportunity culture
- Increasing the potential for worldwide recognition

The Process of Implementation & Certification of a Quality Management System (QMS)



13. CONFORMITY ASSESSMENT

Conformity assessment is defined as any activity concerned with determining directly or indirectly that the relevant requirements are fulfilled. (*see page 3*)

> The essential objective of a conformity assessment procedure is to enable the public authorities to ensure that products placed on the market conform to the requirements, as expressed in the provisions of the European Directives, with particular reference to the health and safety of users and consumers

A manufacturer or supplier may declare, after performing the necessary product evaluations, through a Declaration of Conformity, that the product meets the essential requirements of a directive. As the risk of injury increases, the level of complexity of the conformity assessment process (and the cost) increases with it. The applicable directive will be the guide to the level of risk involved and the methods of conformity assessment that may be employed.

The Global Approach

In the European Union countries, the rationale for the New Approach Directives was to eliminate differences between national laws, thereby eliminating barriers to trade between the Member States. But, differences in national standards, testing and certification procedures proved to be some of the root causes of barriers to trade and it followed that a new, integrated scheme for technical harmonisation, had to be implemented.

The new scheme was embodied in two Decisions: (1) **the Module Decision**, and (2) the regulation on **CE Marking**. The new policy was called the Global Approach, which incorporated conformity assessment procedures directly into the New Approach Directives.

The Module Decision sets out the criteria and guidelines for conformity assessment procedures to be used in the New Approach Directives.

Conformity assessment can be subdivided into modules, which relate to the **design phase** of products and to their **production phase**, as follows:

DESIGN PHASE	Internal Control of Production	Type Examination	Unit Verification	Full Quality Assurance
Manufacturer	-Keeps technical documentation at the disposal of national authorities	-Submits to notified body -Technical documentation -Type	-Submits technical documentation	-Operates an approved quality system (QS) for design
Notified Body	-Intervention of notified body	-Ascertains conformity with essential requirements / Carries out tests, if necessary / Issues EC type-examination certificate		-Carries out surveillance of the QS / Verifies conformity of the design / Issues EC design examination certificate

PRODUCTION PHASE	Manufacturer	Notified Body
Internal Control of Production	-Declares conformity with essential requirements -Affixes the CE mark	-Tests on specific aspects of the product -Product checks at random intervals
Conformity to type	-Declares conformity with approved type -Affixes the CE mark	
Production quality assurance	-Operates an approved quality system (QS) for production and testing -Declares conformity with approved type -Affixes the CE mark	-Approves the QS -Carries out surveillance of the QS
Product quality assurance	-Operates an approved quality system (QS) for inspection and testing -Declares conformity with approved type, or to essential requirements -Affixes the CE mark	-Approves the QS -Carries out surveillance of the QS
Product verification	-Declares conformity with approved type, or with essential requirements -Affixes the CE mark	-Verifies conformity -Issues certificate of conformity
Unit verification	-Submits product -Declares conformity -Affixes the CE mark	-Verifies conformity with essential requirements -Issues certificate of conformity
Full quality assurance	-Operates an approved QS for production and testing -Declares conformity -Affixes the CE mark	-Carries out surveillance of the QS

As a general rule, a product should be subject to both Design & Production phases (as applicable), prior to being placed on the market, if the results are positive. There are a number of modules which cover the two phases, in a variety of ways.

14. CE MARKING
A TRADE PASSPORT TO THE EUROPEAN UNION

What is CE marking?

The CE mark is a mandatory European marking, for certain product groups to indicate conformity with the essential health and safety requirements, set out in the European Directives. (*see page 3*)

The CE mark must be affixed to a product if it falls under the scope of about 20 so-called 'New Approach' Directives. Without the CE marking and thus without complying with the provisions of the Directives, the product may not be placed on the market or put into service in the 25 Member States of the European Union, as well as in EFTA countries.

> However, if the product meets the provisions of the applicable European Directives and the CE mark is affixed to it, these countries may not prohibit, restrict or impede the placing of the product, in the market or putting it into service. Thus, CE marking can be regarded as the product's trade passport for Europe.

The CE mark is not a quality-mark. First, it refers to the safety rather than the quality of a product. Second, most quality markings are voluntary, as opposed to CE marking, which is mandatory for the products it applies to. CE indicates conformity with mandatory European safety requirements. European conformity is certified by following clear and understandable procedures, the so-called 'conformity assessment procedures' *(see below)*.

Why CE marking?

The European CE certification procedure has been established to:

1. Harmonise all varying national regulations for consumers and industrial products in European Member States, so that the Single Market is encouraged
2. Bring about cost savings for producers
3. Enhance the safety of products
4. Supply public bodies with a uniform procedure that can be checked and verified

Formerly, the Member States of the EU set product requirements and test procedures. This meant that, for example, companies that wanted to sell their products on the European market sometimes had to deal with more than ten different technical requirements or procedures for just one product.

The existence of all the different national legislation was contrary to the aim of the European Union in realising one Single Market, in which there would be free circulation of goods (as well as free circulation of persons, services and capital).

With the help of conformity assessment procedures, the authorities can ascertain that the products that are placed on the market comply with the requirements, as stated in the regulations of the directives.

The steps for CE marking and CE certification procedures

Before the CE marking may be affixed to a product, the essential requirements of the applicable European Directive must be met. Moreover, following the testing and/or certification procedure, product conformity compliance must be proved. Besides some administrative steps to be followed, this can mean that a risk analysis must be performed or that the compliance must be tested in a laboratory.

Products which CE marking applies to

The CE mark is applicable to the following - medical devices, machinery, industrial installations, toys, electrical equipment, electronics, domestic appliances, pressure equipment, personal protective equipment, recreational craft, refrigerators, etc. The complete list of the new approach directives is as follow:

1. Low Voltage
2. Simple Pressure Vessels
3. Safety of toys
4. Construction products
5. Electromagnetic compatibility (EMC)
6. Machinery
7. Personal protective equipment (PPE)
8. Non-automatic weighing instruments
9. Active implantable medical devices
10. Appliances burning gaseous fuels
11. Efficiency requirements for new hot-water boilers fired with liquid or gaseous fuels
12. Explosives for civil uses
13. Medical devices
14. Equipment for potentially explosive atmospheres (ATEX)
15. Recreational crafts
16. Lifts
17. Pressure equipment
18. In vitro diagnostic medical devices

19 Radio Equipment and Telecommunications Terminal Equipment and the Mutual Recognition of their Conformity
20 Cableway installations designed to carry persons
21 Measuring instruments

The CE marking does not apply to items such as cosmetics, chemicals, pharmaceuticals, and foodstuffs.

Requirements with regard to the affixing of the CE marking logo

The CE marking must be affixed to the product, to its data plate or, where this is not possible or not warranted, to its packaging, it must also be affixed to the accompanying documents by the manufacturer, the authorised representative in the EC or, in exceptional cases, by those responsible for placing the product on the market.

The CE marking must be affixed visibly, legibly and indelibly. Where special provisions do not impose specific dimensions, it must have a height of at least 5 millimetres.

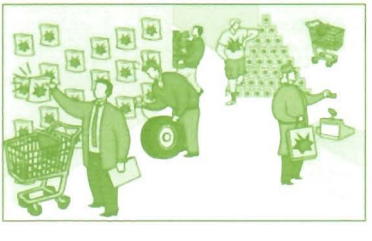
15. MARKET SURVEILLANCE

Principles

The main goal of the New Approach Directives is to ensure that products, which freely circulate in EU markets, have a proper level of safety.

The Global Approach can never work properly without having an adequate feedback system.

This system has been created by the European Commission and called **market surveillance**. Only the national authority has the responsibility for market surveillance activities.



Market surveillance is a necessary element to correctly implement the above-mentioned principles.

Considering that free competition cannot exist without fair competition, market surveillance is also of interest for serious manufacturers, as it prevents competitors from cutting prices, arising from the bypassing of essential requirements.

Market Surveillance Actors

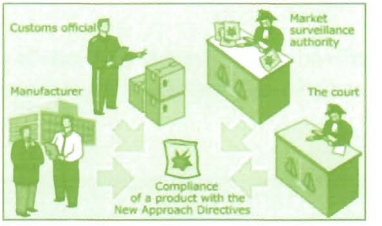
There are several persons who check the compliance of a product under the New Approach directives:

The **manufacturer**, before the product has been placed on the market

The **customs official**, for products originating from outside the EU

The **market surveillance authority**, after the product has been brought onto the market

The **courts**, when an incident occurs and legal action results



Customs officials have the right to stop products coming into the European Community from third countries, for two reasons:

1. Products which display certain characteristics that would give rise to serious doubts as to the existence of a serious and immediate risk to health and safety. If a product is found to cause a risk to health or safety, the customs officials will mark the invoice with "Dangerous product - release for free circulation not authorised - Regulation (EEC) N° 339/93"

2. Products are not accompanied by a document or marked in accordance with applicable rules on product safety.

If officials do not declare an infraction on import or product safety laws within a short period of time, the product must be allowed for free circulation throughout the single market

Aside from the standard import documents, CE-marked goods should, as a general rule, be accompanied by the EC declaration of conformity.

If a shipment is not accompanied by the necessary documents, the invoice is stamped "Product not in conformity - release for free circulation not authorised - Regulation (EEC) N° 339/93".

Co-operation in the field of Market Surveillance

Market surveillance is still, for a large part, under the jurisdiction of the Member States or their local authorities.

There is an obvious need for close co-operation in the field of market surveillance, but this co-operation has not yet been institutionalised. To this end, several channels of communication have been installed, such as RAPEX, a rapid exchange of information on dangers arising from the use of consumer products.

The Member State must provide the necessary legal and administrative means to guarantee the compliance of the products on the market with the directives.

> So different Member States may have different fines and/or sanctions for the same infraction, the same directive might fall under the jurisdiction of different authorities in the 25 Member States.

There is a clear distinction between conformity assessment, which takes place before the product is brought onto the market, and market surveillance, which takes place after the product has been brought onto the market.

The authorities cannot exercise any pre-market inspections or other operations during the design and production stages. This does not, however, mean that they can be refused access to the production process. In case of an investigation, the surveillance authority must be entitled to obtain access to places of manufacture or storage, to receive information, to select a sample and send it for examination and testing. If they have doubts about a product, they will contact both the manufacturer and the notified body.

16. Related WEB SITES

The following web sites are related to the topics of this publication

Association of Lebanese Industrialists
www.ali.org.lb

CE Marking
www.cemarking.net

Chamber of Commerce, Industry and Agriculture of Beirut
www.ccib.org.lb

European Organisation for Quality
www.eoq.org

European Commission
www.europa.eu.int/comm

European Commission Delegation in Lebanon
www.dellbn.cec.eu.int

European Committee for Standardisation (CEN)
www.cenorm.be

European Union
www.europa.eu.int

Globalisation Guide
www.globalisationguide.org

International Accreditation Forum
www.iaf.nu

International Laboratory Accreditation co-operation
www.ilac.org

International Labor Organization (ILO)
www.ilo.org

International Organisation for Standardisation
www.iso.org

Ministry of Economy & Trade, Beirut
www.economy.gov.lb

Quality Programme
www.economy.gov.lb/MOET/English/Panel/Projects/Quality

Syndicate of Lebanese Food Industries
www.slfi.org.lb

World Association for Small and Medium Enterprises (WASME)
www.wasmeinfo.org

World Trade Organistion
www.wto.org